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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,526	05/01/2001	Daniel Santi	300622005400	4025

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,526

Applicant(s)

SANTI ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 in Paper No. 7, filed 9/12/02 is acknowledged.

Claims 9-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the use of "derivative of the second polyketide" renders the claim vague and indefinite because the metes and bounds of what is considered to be a derivative in this context is unclear. Does "derivative" only encompass

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polyketides that are capable of being biosynthetically converted to the other polyketide? Does the conversion encompass only naturally occurring conversion, or does it encompass any conversion, including non-natural conversions? Or, does "derivative" encompass any polyketide that has one or more differences from another polyketide, whether or not the one can be made into the other by biochemical means?

Also, there is no clear positive antecedent basis for "the overproducing cell".

Regarding claims 5-8, there is no clear positive antecedent basis for "the overproducing cell". Also, the amount of polyketide produced is unclear because it is unclear whether the level is relative to the medium used to culture the cell, or relative to an extract made from the cell, for example.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Khosla et al (Applicant reference no. 1, U.S. Patent No. 5,672,491).

Khosla et al teach a method of producing a new polyketide by deleting the entire natural PKS gene cluster of a cell that is optimized to produce a polyketide, and then introducing a functional PKS gene set into the cell, which then produces the new polyketide (columns 11-12). The PKS gene set can comprise native or hybrid combinations of PKS subunits or mutants (and thus would produce a derivative of the second polyketide). A number of polyketides were produced using the method (columns 15-16). In one example of the method, approximately 100 mg of the mixture of polyketides could be easily produced from 1 l of the culture (column 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosla et al (Applicant reference no. 1, U.S. Patent No. 5,672,491) in view of Ziermann et al (Applicant reference no. 3, U.S. Patent No. 6,177,262).

Khosla et al teach a method of producing a new polyketide by deleting the entire natural PKS gene cluster of a cell that is optimized to produce a polyketide, and then introducing a functional PKS gene set into the cell, which then produces the new polyketide (columns 11-12). The PKS gene set can comprise native or hybrid combinations of PKS subunits or mutants (and thus would produce a derivative of the second polyketide). A number of polyketides were produced using the method (columns

15-16). In one example of the method, approximately 100 mg of the mixture of polyketides could be easily produced from 1 l of the culture (column 22).

Khosla et al do not specifically teach the method of producing a first polyketide in which the cell overproduces the second polyketide at a level greater than 10 g/l.

Ziermann et al teach increasing the yields of polyketides produced in host cells by coexpression of the ptpA gene (abstract). This reference teaches that polyketides are a diverse class of compounds with a wide variety of activities, including activities useful for medical, veterinary, and agricultural purposes (column 1) and thus there is a need for host cells that can produce useful polyketides at higher levels than can be achieved with currently available cells (column 2). Ziermann et al teach ptpA coexpression strains that produce over 10 g/l of polyketides (column 13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cells that coexpress the ptpA gene (and which produce a polyketide) taught by Ziermann et al as the cells used in the method of producing a polyketide taught by Khosla et al because Ziermann et al teach that it is within the ordinary skill in the art to coexpress ptpA in a cell that produces a polyketide and Khosla et al teach

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that it is within the ordinary skill in the art to replace the natural PKS gene cluster with an introduced new functional PKS gene set in a cell that produces a polyketide, to make a new polyketide produced by the resulting cell.

One would have been motivated to do so for the expected benefit of increasing the production of the polyketides, such as to exceed 10 g/l, resulting from the method made from the combined teachings of the cited references, which increased production is needed and desirable because polyketides have activities useful for medical, veterinary, and agricultural purposes, as taught by Ziermann et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claims are allowable.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014.

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NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

March 23, 2003